

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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**Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices
Advisory Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 16, 2001, 10 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

Contact: Michael Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8611, ext. 140, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12624. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a high-frequency ventilator used in the treatment of acute respiratory failure in adults. Background information and questions for the committee will be available to the public on July 13, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

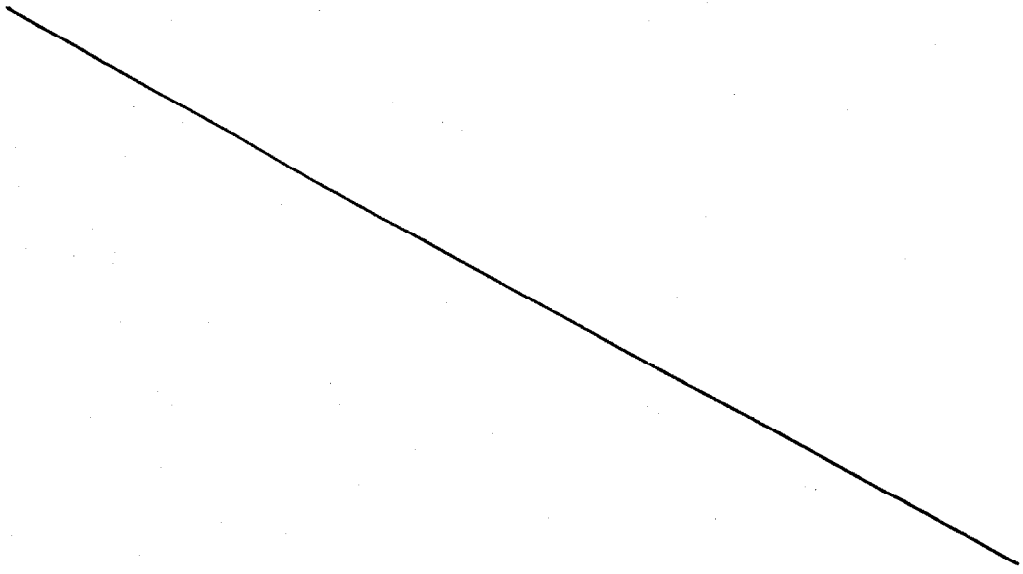
Procedure: On July 16, 2001, from 12 a.m. to 5 p.m., the meeting is open to the public.

Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Written submissions may be made to the contact person by July 9, 2001. Oral presentations from the public will be scheduled between approximately 12:15 p.m. and 12:45 p.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 9, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On July 16, 2001, from 10 a.m. to 12 noon, the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future anesthesiology and respiratory therapy device submissions.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).



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Dated: 6/19/01
June 19, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Bonnie Malkin

[Signature]

Bonnie Malkin,
Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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